



JPW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Ranatunge et al**

Application No: **10/608,333**

Group Art Unit: **1626**

Filed: **June 30, 2003**

Examiner: **T.A. Solola**

For: **Oxime and/or Hydrozone containing Nitrosated and/or Nitrosylated
Cyclooxygenase-2 Inhibitors, Compositions and Methods of Uses**

Attorney Docket No: **102258.153 US1**

Commissioner of Patents
PO Box 1450
Alexandria, VA 22313-1450

**Provisional Response to Restriction Requirement and
Request for Reconsideration of Restriction Requirement Under 37 C.F.R. § 1.143**

I. Introductory Comments

This response is submitted in reply to the Restriction Requirement dated November 19, 2004, for which a response is due on or before December 19, 2004.

No fee is believed to be due; however, the Commissioner is authorized to charge any necessary fees or credit any overpayments to Deposit Account No. 08-0219 to maintain the pendency of the present application.

II. Request for Reconsideration of Restriction Requirement

Under 37 C.F.R. §1.143, Applicants respectfully request reconsideration of the restriction requirement dated May 27, 2004.

The examiner restricted the invention as follows:

Group I	Claims 1-2, 14-16, 28-39, 55-57	Compounds and compositions of Formula I
Group II	Claims 1-2, 14-16, 28-39, 55-57	Compounds and compositions Formula II
Group III	Claims 1-2, 14-16, 28-39, 55-57	Compounds and compositions of Formula III

Provisional Response to Restriction Requirement**Application No. 10/608,333****Page 2 of 6**

Group IV	Claims 1-2, 14-16, 28-39, 55-57	Compounds and compositions of Formula IV
Group V	Claims 1-2, 14-16, 28-39, 55-57	Compounds and compositions of Formula V
Group VI	Claims 1-2, 14-16, 28-39, 55-57	Compounds and compositions of Formula VI
Group VII	Claims 1-2, 14-16, 28-39, 55-57	Compounds and compositions of Formula VII
Group VIII	Claims 1-2, 14-16, 28-39, 55-57	Compounds and compositions of Formula VIII
Group IX	Claims 1-2, 14-16, 28-39, 55-57	Compounds and compositions of Formula IX
Group X	Claims 1-2, 14-16, 28-39, 55-57	Compounds and compositions of Formula X
Group XI	Claims 1-2, 14-16, 28-39, 55-57	Compounds and compositions of Formula XI
Group XII	Claims 1-2, 14-16, 28-39, 55-57	Compounds and compositions of Formula XII
Group XIII	Claims 1-2, 14-16, 28-39, 55-57	Compounds and compositions of Formula XIII
Group XIV	Claims 1-2, 14-16, 28-39, 55-57	Compounds and compositions of Formula XIV
Group XV	Claims 1-2, 14-16, 28-39, 55-57	Compounds and compositions of Formula XV
Group XVI	Claims 1-2, 14-16, 28-39, 55-57	Compounds and compositions of Formula XVI
Group XVII	Claims 3, 17 and 40	Method of reducing inflammation, pain or fever
Group XVIII	Claims 4-5, 18-19, 41-42	Method of treating GI disorders
Group XIX	Claims 6-8, 20-21, 43-44	Method for facilitating wound healing
Group XX	Claims 8, 22, 45	Method of treating or reversing renal and/or respiratory toxicity

Group XXI	Claims 9-10, 23-24, 46-47	Method of treating disorders resulting from elevated COX-2
Group XXII	Claims 11, 25, 48	Method of treating cancers
Group XXIII	Claims 12, 26, 49	Method of treating central nervous disorders
Group XXIV	Claims 13, 27, 50	Method of inhibiting platelet aggregation
Group XXV	Claims 51-54, 58	Kits for the compounds of Formulas I-XVI

The claims in the pending application are directed to compounds and compositions comprising **nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compounds**, kits comprising nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compounds, and the methods of use for the compounds and/or compositions.

III. Restriction is Not Proper When the Claims are Related

As stated in MPEP §808.02, “[w]here, as disclosed in the application, the several inventions claimed are related, and such related inventions are not patentably distinct as claimed, restriction under 35 U. S. C. §121 is never proper (MPEP §806.05).”

All the pending claims are related. Thus, the restriction requirement is not proper. To show that the inventions are distinct, the Examiner must show either that (1) there is a separate classification of the claims; (2) a separate status in the art when they are classifiable together; or (3) a different field of search. *In re Kase*, USPQ2d 1063 (US PTO Director, 2004).

None of these three criteria have been shown with the claims of this application:

If the nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compounds and compositions are allowable, then all the kits and methods of use for these compositions would also be allowable. In other words, every pending claim that requires a **nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compound** would also be allowable. *In re Kase*, USPQ2d 1063 (US PTO Director, 2004).

A search of the prior art for the nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compounds and compositions would necessarily encompass a search of the prior art for their

methods of use and the kits comprising the compounds. Thus, the prior art for the nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compounds and compositions of Groups I–XVI of Formulas I–XVI respectively, will also be the same prior art for their methods of use and kits for the compositions comprising the nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compounds (i.e., Groups XVII–XXV).

III. Proposed restriction requirement

Applicants respectfully propose the following restriction requirement:

Group I	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula I
Group II	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula II
Group III	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula III
Group IV	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula IV
Group V	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula V
Group VI	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula VI
Group VII	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula VII
Group VIII	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula VIII
Group IX	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula IX
Group X	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula X
Group XI	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula XI
Group XII	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula XII

Group XIII	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula XIII
Group XIV	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula XIV
Group XV	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula XV
Group XVI	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula XVI

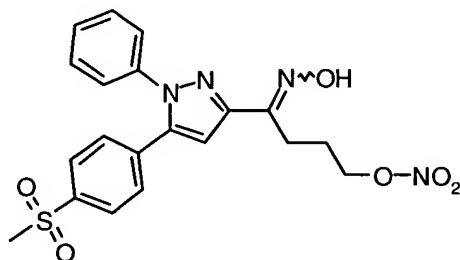
IV. Provisional Response to Restriction Requirement

Applicants provisionally elect Group II, claims 1-2, 14-16, 28-39, 55-57 drawn to the compounds and compositions of Formula II, with traverse.

V. Election of Species

In response to the election of species requirement, Applicants elect the nitrosated nonsteroidal antiinflammatory compound of Formula A, 1-(3-(1-(hydroxyimino)-4-(nitrooxy)butyl)-1-phenylpyrazol-5-yl)-4-(methylsulfonyl)benzene, with traverse.

This compound has the structure:



(A)

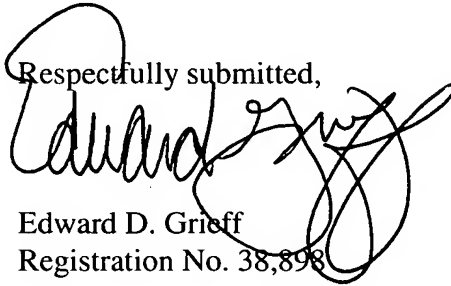
The synthesis of this compound is described in Example 1 of the specification at page 107, line 13 to page 110, line 18.

VI. Conclusion

Applicants respectfully request that the restriction requirement be withdrawn and be replaced with Applicant's proposed restriction requirement.

An early and favorable consideration and allowance of the pending claims is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Edward D. Grieff', is written over the typed name and registration number.

Edward D. Grieff
Registration No. 38,898

Date: December 16, 2004
WILMER CUTLER PICKERING
HALE AND DORR LLP
1455 Pennsylvania Avenue, NW
Washington, DC 20004
Phone: (202) 942-8453